



UNITED STATES PATENT AND TRADEMARK OFFICE

cl
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/786,850

02/24/2004

Allan Svendsen

10203.204-US

3589

25908

7590

06/16/2006

NOVOZYMES NORTH AMERICA, INC.

500 FIFTH AVENUE

SUITE 1600

NEW YORK, NY 10110

EXAMINER

MOORE, WILLIAM W

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/786,850

Applicant(s)

SVENDSEN ET AL

Examiner

William W. Moore

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2006 and 13 April 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-78 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 48-68, 73, 74 and 78 is/are rejected.
7) ☒ Claim(s) 69-72 and 75-77 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 20060413.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's amendments in the Reply filed 29 March 2006 cancel the original claims 1, 2, 19, 20, and 24 and present the new claims 48-78. The new claims are free of the objections of record to the specification and are free as well of the prior art rejections of record based on disclosures of Servant et al., Wati et al., Davail et al., and Narinx et al. The new claims are not subject to the rejections of record under 35 U.S.C. § 112, first and second paragraphs, because the specification describes, see pages 18 and 19, the preparation of variant TY145 subtilases having concurrent additions and deletions of as many as 28 amino acids that remove, or add, ion-binding sites in the native TY145 subtilase having the sequence set forth in SEQ ID NO:1.

Election

Applicant affirms the telephonic election made 7 September 2005 of the modified species of TY145 protease having an amino acid sequence modification at position 171 of SEQ ID NO:1 at page 6 of the Response filed 29 March 2006. On 29 September 2005 a first Office communication on the merits that considered the elected species was mailed wherein no rejection of a modification at position 171 of SEQ ID NO:1 was stated that was based on a prior art disclosure. New claims 48-58, 60-74 and 76-78 presented in the Response filed 29 March 2006 do not, however, require any modification at position 171 of SEQ ID NO:1 nor are claims 59 and 75 specifically drawn to a modification at position 171 of SEQ ID NO:1. Indeed, claims 59, 69, 70, 72, 75, and 76 recite numerous amino acid positions for modification that were present in any of the claims 1, 2, 19, 20, or 24 presented for examination in the Preliminary Amendment filed 24 February 2004. These are the positions 31, 35, 36, 79, 80, 81, 106, 139, 164, 165, 166, 167, 168, 172, 173, 174, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187,

Art Unit: 1656

188, 189, 190, 191, 193, 198, 199, 202, 204, 207, 221, 222, 223, 224, 225, 226, 227, 228, 229, 247, 248, 249, 250, 251, 252, 254, 268, 269, 270, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306 and 307 of SEQ ID NO:1. Claim 70 recites a further four positions for modification absent from claim 59 and not even present in any of the original claims 1, 2, 19, 20, and 24: positions 26, 95, 203 and 292 of SEQ ID NO:1.

The newly submitted claims 69-74 and 76 are directed in part to an invention that is independent or distinct from the invention originally elected for the following reasons: None of claims 69-74 and 76 recites a modification at position 171 of SEQ ID NO:1 that represents the elected species. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 69-74 and 76 are in part withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Information Disclosure Statement

Applicant's Information Disclosure Statement [IDS] filed on 13 April 2006, citing five journal publications, is hereby acknowledged. The first page of the two Forms PTO-1449 submitted in the IDS and provided in executed form with this communication is lined-through because no references were cited on that page.

Claim Objections

Claims 69, 70, 72, and 75-77 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. Claims 69-70, 72, and 75-77 recite several positions for substitution not present in claim 59 from which they depend.

Art Unit: 1656

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Applicant's presentation of the new claims 48-58 describing no particular variants, stating no negative limitations, and referring to SEQ ID NO:1, necessitates this new ground of rejection. Claims 48-58 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 7-9 of U.S. Patent No. 5,362,414. Although the conflicting claims are not identical, they are not patentably distinct from each other because the more broadly-stated patent claims embrace the subject matter of claims 48-58 herein where the TY145 protease of the patent claims meets limitations of claims 48-58 herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1656

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 48-58 are rejected under 35 U.S.C. § 102(e) as being anticipated by Outtrup et al., US 5,362,414, made of record herewith.

Applicant's presentation of the new claims 48-58 describing no particular variants, stating no negative limitations, and referring to SEQ ID NO:1 necessitates this new ground of rejection. Outtrup et al., '214, disclose the isolation of a protease from *Bacillus* sp. TY145 and the preparation of detergent compositions comprising the protease in columns 3-6 and claims 1, 2 7 and 8, which cannot be distinguished on the present record from a protease of claims 48-57, and a detergent composition of claim 58, herein thus are considered to anticipate the invention of claims 48-58.

Claims 48-58 are rejected, essentially for reasons of record, under 35 U.S.C. § 102(e) as being anticipated by Outtrup et al., US 6,511,371, made of record herewith.

Applicant's arguments filed 29 March 2006 have been fully considered but they are not persuasive. Applicant suggests at page 8 of the Response that Outtrup et al., '371, do not "disclose or suggest the protease variants" of the new claims but the new claims 48-58 require no variant subtilase thus the subtilase amino acid sequence in SEQ ID NO:2 of Outtrup et al. which is identical to SEQ ID NO:1 herein meets the limitations of claims 48-57 herein. Outtrup et al. also disclose preparation of a detergent composition comprising this protease in Examples 2-4, meeting the limitations of claim 58.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1656

Claims 59-68, 73, 74, and 78 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Outtrup et al., US 6,511,371, as applied to claims 48-58 above, in view of Wintrode et al., 2001, made of record with Applicant's disclosure Statement.

Applicant's presentation of new claims 59-68, 73, 74, and 78 describing particular TY145 protease variants by reference to specific positions in the amino acid sequence of SEQ ID NO:1 necessitates this new ground of rejection. None of claims 59-68, 73, 74, and 78 require a particular substituent at any of the recited amino acid positions. The teachings of Outtrup et al., '731, of the psychrophilic TY145 protease amino acid sequence set forth in their SEQ ID NO:2, which is SEQ ID NO:1 herein, and the preparation of a detergent composition comprising the isolated TY145 protease are taken as before and the further teachings of Outtrup et al. of the preparation of variants in order to improve their "wash performance in cleaning or detergent composition[s]" at cols. 8-10 is now emphasized. Wintrode et al. teach, see the Abstract, Table 1, and their discussion at pages 6 and 7, that the directed replacement of one or more serines throughout the amino acid sequence of a psychrophilic microbial protease produced variants having greater stability at higher temperatures than the native protease could withstand without loss of activity. It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teachings of Wintrode et al. to the teachings of Outtrup et al., '731, and to select one or more serines present within the amino acid sequence of SEQ ID NO:2 of Outtrup et al., '371, for substitution with, e.g., alanine, threonine, or isoleucine as Wintrode et al. teach as stabilizing substituents in Table 1, because such an artisan would have been motivated to prepare a TY145 variant with improved thermal stability for introduction in a detergent composition suitable for standard wash temperatures. Such an artisan would have had a reasonable expectation of success in achieving a variant TY145 protease having improved thermal stability by making substitutions of alanine, threonine, and isoleucine for serines throughout the amino acid sequence of SEQ ID NO:2 of Outtrup et al., including the

Art Unit: 1656

serines at, e.g., positions 48, 58, 65, 86, 111, 114, 129,, 140, 143, 144, 148, 152, 171, 166 and 270 of SEQ ID NO:1 herein because all six of the substitutions of serine that Wintrode et al. made in a psychrophilic microbial protease improved its thermal stability.

Conclusion

Claim 71 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

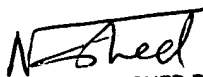
THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore
8 June 2006


NASHAAT T. NASHED PHD.
PRIMARY EXAMINER